K013136

PREMARKET NOTIFICATION [510(k)] SUMMARY

NOV 2 6 2001

A. SUBMITTER INFORMATION:

date of summary: 11-04-00
submitted by: VON ZEPPELIN
CHIRURGISCHE INSTRUMENTE GMBH
Gistlstrasse 99
82049 Pullach- Germany -
Tel.: +49 / 89 / 7936880
Fax: +49 / 89 / 7938545
establishment registration no.: 8010947
contact person: Mr. von Zeppelin, President

B. DEVICE INFORMATION

Trade Name Aneurysm Clips: Perneczky Titanium Aneurysm Clips
see "Appendix 3"

Common Name: "Aneurysm Clips"

Class of Device: Class II

Classification Name: Aneurysm Clip

Equivalent Device: Yasargil Titanium Aneurysm Clips *(#K983758)* by Aesculap
Spetzler Ti 100 Aneurysm Clips *(#K955064)* by Elekta
Sugita Aneurysm clips *(#K782040)* by Down Surgical, by Mizuho Medical
Codman occlusion clips *(#K760771)* such as Sundt-Kees Slim-Line Aneurysm Clips and McFadden Vari-Angle Aneurysm clips.

C. DEVICE DESCRIPTION:

These titanium alloy aneurysm clips will be available as temporary or permanent in STANDARD OR MINI/ MICRO models.

D. INTENDED USE OF DEVICE:

The intended use of the Perneczky Titanium Alloy aneurysm clips is to occlude cerebral aneurysms in either a temporary or permanent manner. They are applied by Zeppelin clip appliers.

E. TECHNOLOGICAL CHARACTERISTICS

The additional patterns of Perneczky Titanium Alloy aneurysm clips do not incorporate any new technological characteristics when compared to Zeppelin's current Perneczky Titanium or Phynox aneurysm clips, or to other legally marketed devices. The titanium alloy clips share similar tolerances, manufacturing controls, packaging and labeling as the current Phynox and Titanium aneurysm clips.

F. MATERIAL COMPOSTION / BIOCOMPATIBILITY

The material composition is titanium alloy (Ti6AL4V). The alloy composition and properties conforms with ISO Standard 5832/3: *"Implants for Surgery Metallic Materials – Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy"* and ASTM standard F136-98e1: *"Standard Specification for Wrought Titanium-6 Aluminium-4 Vanadium ELI (Extra Long Interstitial) Alloy (UNS R56401) for Surgical Implants Applications"*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2001

Mr. Dieter von Zeppelin
President
von Zeppelin Chirurgische Instrumente GmbH
Gistlstrasse 99
82049 Pullach / Germany

Re: K013136
Trade/Device Name: Perneczky Titanium Aneurysm Clips
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm Clip
Regulatory Class: Class II
Product Code: HCH
Dated: August 23, 2001
Received: September 19, 2001

Dear Mr. von Zeppelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K013136

Device Name: Perneczky Titanium Aneurysm Clips

Indications for Use:

The Perneczky Titanium Aneurysm Clips are devices used to occlude an intracranial aneurysm (a balloon like sac formed on a blood vessel) to prevent it from bleeding or bursting. These titanium alloy aneurysm clips will be available as temporary or permanent devices.

(Signature)

Dieter von Zeppelin
(Type Name)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ____ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013136